REMARKS

Claims 1-10 and 13 are currently pending. Claims 11, 12, and 14-16, withdrawn pursuant to a restriction requirement, are canceled, without prejudice to the prosecution of their subject matter in other patent applications. Claims 1 and 13 have been amended. The amendments to claims 1 and 13 do not constitute new matter.

The Examiner has acknowledged the claim for foreign priority based on application A 89/2001, but has mistakenly indicated, first, that the priority application is Australian, and second, that the priority document has not been supplied. As stated in the claim for priority supplied by preliminary amendment and in the filing receipt, the priority application is Austrian. Further, the priority document was submitted on December 9, 2003 (copy of submission attached), and was received by the Patent Office as evidenced by the date-stamped return receipt postcard (copy attached). Please ensure that the submission of the priority document is of record.

The Examiner has rejected claims 1-10 and 13 over 35 U.S.C. § 112, second paragraph, as being indefinite due to the terms "tissues," "microparticles," and "polyacton." The Examiner has rejected claims 1-9 under 35 U.S.C. § 102(b) as anticipated over U.S. Patent No. 5,165,938 to Knighton ("Knighton"). The Examiner has rejected claims 1-4 and 6-9 under 35 U.S.C. § 102(b) over U.S. Patent No. 5,185,160 to Chao ("Chao"). The Examiner has rejected claims 1-10 and 13 under 35 U.S.C. § 103(a) over Knighton and Chao in view of U.S. Patent No. 5,697,980 to Otani ("Otani"). For the reasons detailed below, the rejections should be withdrawn and the claims allowed to issue. Entry of the foregoing amendments is respectfully requested.

The Claims Are Definite

The Examiner has rejected claims 1-10 and 13 over 35 U.S.C. § 112, second paragraph, as being indefinite due to the terms "tissues," "microparticles," and "polyacton."

In particular, the Examiner states that claim 1 is indefinite due to the term "tissues." The Examiner states that "the scope of generic tissue(s) other than blood cells is broad beyond some reasonable limits since animal tissues contain millions of various 'moieties' and compounds." Applicants note that the term "tissues" has been deleted from claim 1, and the Examiner rejection with regard to this term has been rendered moot. Claim 1 has also been amended to recite "activated blood cells." Support for this amendment can be found in the specification at, for example, page 5, second paragraph.

The Examiner also states that the term "microparticles" is indefinite because the "contents or components of 'microparticles' are not disclosed in the as-filed specification." Applicants assert that the term "microparticles" has a very definite meaning to a person of ordinary skill in the art. Applicants would like to draw the Examiner's attention to Horstman and Ahn, Critical Reviews in Oncology/Hematology, 1999, 30:111-142 ("Horstman"), which is submitted herewith. Horstman clearly summarizes the term "microparticles" as would be understood by a person of ordinary skill in the art at the time of filing the present application. Horstman describes microparticles as "submicroscopic... membrane vesicles released during activation, and [carrying] at least some antigens characteristic of platelets." See Horstman at page 113. Horstman goes on to describe and characterize microparticles in great detail, as well as methods of purifying the microparticles. See Horstman at pages 119-125. Accordingly, Applicants submit that a person of ordinary skill in the art would understand the metes and

bounds of the term "microparticles" based upon the state of the art at the time of filing, as evidenced by Horstman.

The Examiner states that the term "polyacton" in claim 13 is indefinite because a "polymer with this name does not exist or, in alternative, the term is misspelled." Applicants note that the term "polyacton" in claim 13 has been amended to read "polyactin." References to the term "polyacton" in the specification have also been amended to refer to "polyactin." These amendments correct obvious typographical errors.

The Claims are Novel

The Examiner has rejected claims 1-9 under 35 U.S.C. § 102(b) as anticipated over U.S. Patent No. 5,165,938 to Knighton ("Knighton"). The Examiner states:

> "The drug composition contains 'microparticles' derived from platelet-rich plasma after activation and centrifugation. The 'microparticles' are mixed with microcrystalline collagens and frozen.... The drug composition is made under sterile condition.... Blood is collected from normal patients that are not diagnosed with viral diseases and, thus, virus depleted or virus free. The cited patent discloses that drug composition contains growth factors PDAF and PDGF or substances promoting wound healing. Fibrinogen and thrombin are inherent components of a product derived from platelet rich plasma. Proteins and/or glycoproteins of platelet rich plasma fall within the meaning of generic organic polymers as claimed. The drug composition contains inorganic compounds or inorganic salts.... The cited patent teaches the use of composition in conjunction with biodegradable dressings and implantable devices...." (Citations omitted).

The Examiner asserts that Knighton anticipates the claimed invention.

Applicants assert that Knighton does not anticipate the present invention. Anticipation requires that each and every element of the rejected claim(s) be disclosed in a single prior art reference. See M.P.E.P. § 2131 (8th Ed. Rev. 2, May 2004). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2

USPQ2d 1051, 1053 (Fed. Cir. 1987). Every element of the claimed invention must literally be present, arranged as in the claim. *Perkin Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894, 221 USPQ 669, 673 (Fed. Cir. 1984).

Applicants submit that Knighton does not teach all of the limitations of the rejected claims. Unlike the present claims, Knighton does not disclose a composition that "has been subjected to a procedure selected from the group consisting of virus inactivation and virus depletion," as recited in claim 1. Although the Examiner states that the blood "is collected from normal patients that are not diagnosed with viral diseases and, thus, virus depleted or virus free," this is insufficient to satisfy the limitations of the present claims. The Examiner has not cited any portion of Knighton which indicates that the patients from which the blood is derived are free from viral infection. Even if Knighton did have support for such a statement, the fact that a particular blood sample is derived from a source that is assumed to be virus free is not the same as virus depletion or virus inactivation, which actively remove or inactivate viruses which may be present. See specification at, for example, pages 6-7. Also see Knighton at col. 5, lines 50-63 where the possibility of viral infection is acknowledged. Rather than teaching viral inactivation or depletion, Knighton addresses the problem in a different way, by recommending use of autologous platelets. Accordingly, Knighton does not teach all of the limitations of the present invention.

Because viral inactivation or depletion is not explicitly taught by Knighton, the Examiner is essentially contending that the virus inactivation or depletion step is inherently supplied by Knighton. However, for inherent anticipation, the "inherent" feature must necessarily be present in each instance. *In re Robertson*, 169 F.3d 743, 49 USPQ.2d 1949, 1950-1951 (Fed. Cir. 1999). Viral inactivation and/or depletion is not necessarily present in the method of preparing the

compositions of Knighton, and in fact, as noted above, viral inactivation and/or depletion is not set forth by Knighton as a method of removing or inactivating viruses which may be present. As such, Knighton cannot inherently anticipate the present invention.

The Examiner has rejected claims 1-4 and 6-9 under 35 U.S.C. § 102(b) over U.S. Patent No. 5,185,160 to Chao ("Chao"). The Examiner asserts that Chao teaches all of the limitations of the present invention, and asserts that "[a]lthough the particular application of the cited product relates to transfusion as intended to reduce bleeding time, the bleeding reducing drug would clearly be suitable in wound healing."

Applicants assert that Chao does not teach all of the limitations of the present invention. Applicants note that the disclosure of Chao is distinct from the present invention, because, although Chao refers to "microparticles," the microparticles of Chao are not the same as the microparticles of the present invention. The microparticles of Chao are platelet membrane fractions derived from platelet preparations which are subjected to various treatments, resulting in platelet membrane fragments. See Chao, for example, at col. 2, lines 27-40. The microparticles of Chao are prepared by disrupting the plasma membrane, which results in the loss of the cytoplasm and cytoplasmic moieties, to form "ghost platelets." See Chao, for example, at col. 4, lines 17-39. In contrast, the present invention claims microparticles which are portions of the plasma membrane which contain cytoplasmic moieties; these microparticles are released from the platelets by exocytosis, that is, without physical disruption of the plasma membrane, upon treatment with agents such as thrombin. See the specification, for example, at page 1; see also Horstman at page 113 (microparticles are "membrane vesicles released during activation, and [carrying] at least some antigens characteristic of platelets.") (emphasis added).

Thus, the microparticles of Chao are distinct from the microparticles of the present invention, and accordingly Chao does not teach all of the limitations of the present invention.

Based upon the foregoing, Applicants submit that the present invention is not anticipated by Knighton or Chao, and respectfully request withdrawal of the rejections.

The Claims Are Not Obvious

The Examiner has rejected claims 1-10 and 13 under 35 U.S.C. § 103(a) over Knighton and Chao in view of U.S. Patent No. 5,697,980 to Otani ("Otani"). The Examiner states that Knighton and Chao teach all of the limitations of the present invention, as described above, "[b]ut the cited patents are missing particular disclosure about the use of titanium, apatite and organic polymer "polyactone" as material for carriers and/or medical devices." The Examiner asserts that Otani provides the missing limitations, and that it would have been obvious for a person of ordinary skill in the art to combine the references to reach the present invention.

Applicants disagree with the Examiner, and submit that the Examiner has not set forth a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, the Examiner must meet three criteria. The Examiner must establish that (1) there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there is a reasonable expectation of success; and (3) the prior art reference (or references when combined) teach or suggest all the claim limitations. See MPEP §§ 706.02(j) and 2143. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q2d 1438 (Fed. Cir. 1991).

There is no suggestion or motivation to combine these references. As noted above, the microparticles of Chao are platelet membrane fragments derived from disruption of the platelet membranes, and thus are not the same as the microparticles of Knighton. A person of ordinary skill in the art would not be motivated to combine Knighton and Chao, as the microparticles of the two references are different from one another. In fact, Chao teaches away from the present invention, because Chao disrupts the plasma membrane of the platelet cells, resulting in loss of the cytoplasmic moieties. As discussed above, the present invention utilizes microparticles which are released from activated platelets, and contain cytoplasmic moieties.

Furthermore, Otani does not make any reference to the use of the disclosed artificial filling and prosthetic material in conjunction with agents that promote wound healing or tissue regeneration. Similarly, Knighton and Chao do not make any reference to the use of microparticles in an artificial filling and prosthetic material. Thus, there is no suggestion or motivation to combine the references to reach the present invention. Applicants submit that the Examiner is making a determination of obviousness based upon impermissible hindsight, because the references do not provide an "objective reason to combine the teachings of the references." MPEP 2143.01 ("The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.") (emphasis in original).

Applicants submit that a person of ordinary skill in the art would not have a reasonable expectation of success in combining the cited references to reach the present invention. As noted above, the microparticles of Chao and Knighton are different, and are prepared by different processes. The process by which the microparticles of Chao are prepared results in disruption of the plasma membrane, and loss of cytoplasm. As such, the combination of Knighton and Chao

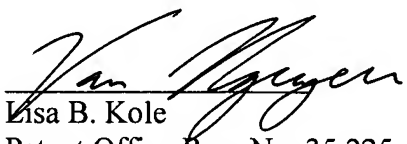
would not result in the microparticles disclosed in the present invention, which contain cytoplasmic moieties. See specification at, for example, page 1; see also Horstman at page 113. Furthermore, there is no teaching or guidance in any of the cited references with regard to the combination of the microparticles in an organic polymer. A person of ordinary skill in the art could not reasonably expect to succeed in such a combination based upon the teachings of the three references, as the references do not provide any teaching or guidance regarding this combination.

Based upon the foregoing, Applicants submit that the present invention is not obvious in over Knighton and Chao in view of Otani, and respectfully request withdrawal of the rejections.

CONCLUSION

Entry of the foregoing amendments and remarks into the file of the above-identified application is respectfully requested. Applicants believe that the invention described and defined by claims 1-10 and 13 are patentable over the rejections of the Examiner. Withdrawal of all rejections and reconsideration of the amended claims is requested. An early allowance is earnestly sought.

Respectfully submitted,



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